April 26, 2023

Olea Medical
% John J. Smith
Partner
Hogan Lovells US LLP
Columbia Square, 555 Thirteenth Street, NW
WASHINGTON DC 20004

Re: K230552
Trade/Device Name: MR DWI/FLAIR Measurement V1.0
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: February 28, 2023
Received: February 28, 2023

Dear John J. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal

statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Daniel M. Krainak, Ph.D.
Assistant Director
Magnetic Resonance and Nuclear Medicine Team
DHT8C: Division of Radiological Imaging
and Radiation Therapy Devices
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below

510(k) Number *(if known)*
K230552

Device Name

MR DWI/FLAIR Measurement V1.0

MR DWI/FLAIR Measurement V1.0 is an image processing application indicated for use in the analysis of:
(1) MR Diffusion-weighted imaging (DWI)
(2) MR FLAIR images.
The device is intended to be used by trained professionals with medical imaging education including, but not limited to, physicians and medical technicians in the imaging assessment workflow:

- computation of the map relative to the water diffusion, i.e., ADC map;
- extraction and communication of metrics derived from the above map, i.e., hypointense area on ADC, and FLAIR series as well as ratios with contralateral information on FLAIR images.

The results of MR DWI/FLAIR Measurement V1.0 are intended to be used in conjunction with other patient information and, based on professional judgment, to assist the clinician in the medical imaging assessment. Trained professionals are responsible for viewing the full set of native images per the standard of care.

The device does not alter the original medical image. MR DWI/FLAIR Measurement V1.0 is not intended to be used as a standalone diagnostic device and shall not be used to take decisions with diagnosis or therapeutic purposes. Patient management decisions should not solely be based on MR DWI/FLAIR Measurement V1.0 results.

MR DWI/FLAIR Measurement V1.0 can be integrated and deployed through technical platforms, responsible for transferring, storing, converting formats, notifying of detected image variations and display of DICOM imaging data.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

510(k) SUMMARY

Olea Medical's MR DWI/FLAIR Measurement V1.0 K230552

Submitter

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Date Prepared: April 19, 2023

Name of Device: MR DWI/FLAIR Measurement V1.0

Common or Usual Name: Picture archiving and communication system (PACS)

Regulation Name: Medical Image Management and Processing System

Regulatory Class: 21 CFR 892.2050

Product Code: LLZ

Predicate Device: Olea Sphere V3.0 (K152602)

Product name	Olea Sphere V3.0
510(k) number	K152602
Trend name	Olea Sphere V3.0
Classification name	System, image processing, radiological
Classification panel	Radiology
CFR code	21 CFR 892.2050
Classification	Class II
Product code	LLZ

Reference Device: MR Diffusion Perfusion Mismatch V1.0 (K223502)

Product name	MR Diffusion Perfusion Mismatch V1.0
510(k) number	K223502
Trend name	MR Diffusion Perfusion Mismatch V1.0
Classification name	System, image processing, radiological
Classification panel	Radiology
CFR code	21 CFR 892.2050
Classification	Class II
Product code	LLZ

A. Indications for Use

MR DWI/FLAIR Measurement V1.0 is an image processing application indicated for use in the analysis of:
(1) MR Diffusion-weighted imaging (DWI)
(2) MR FLAIR images.
The device is intended to be used by trained professionals with medical imaging education including, but not limited to, physicians and medical technicians in the imaging assessment workflow:

- computation of the map relative to the water diffusion, i.e., ADC map;
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The device does not alter the original medical image. MR DWI/FLAIR Measurement V1.0 is not intended to be used as a standalone diagnostic device and shall not be used to take decisions with diagnosis or therapeutic purposes. Patient management decisions should not solely be based on MR DWI/FLAIR Measurement V1.0 results.

MR DWI/FLAIR Measurement V1.0 can be integrated and deployed through technical platforms responsible for transferring, storing, converting formats, notifying of detected image variations and display of DICOM imaging data.

B. Technological Characteristics

The MR FLAIR/DWI Measurement V1.0 pipeline takes a Fluid-Attenuated Inversion Recovery (FLAIR) sequence and a diffusion weighted imaging (DWI) sequence as input and provides automatically-generated relative and normalized FLAIR images.

Olea Medical proposes MR DWI/FLAIR Measurement V1.0 as an image processing application, Picture Archiving Communications System (PACS) software module that is intended for use in a technical environment which incorporates a Medical Image Communications Device as its technical platform.

MR DWI/FLAIR Measurement V1.0 is an executable application which can run on the OLEA Platform. The OLEA Platform is a Medical Image Communications Device and outside the scope of this submission. MR DWI/FLAIR Measurement V1.0 is a docker totally independent from the OLEA platform in which it is integrated and has a dedicated Input/Output channels to be able to be integrated and deployed through any compatible configurable technical platform. Input DICOM images are received via the dedicated file system in which the application is integrated. When launched, the MR DWI/FLAIR Measurement V1.0 will retrieve and automatically analyze the image series. The output images will be sent to the same dedicated file system and can be visualized from any DICOM viewer by loading these results from the allocated file system.

To be used, the MR DWI/FLAIR Measurement V1.0 docker needs an independent technical base, which is provided by a Medical Image Communications Device (MICD). The technical platform allows the docker to:

- receive the inputs
- provide the outputs
- visualize the outputs through Olea Platform viewer and/or export to other third party DICOM viewers.

Among other algorithms, MR DWI/FLAIR Measurement V1.0 includes a diffusion brain extraction tool (BET) applied before outputs computation. This deep learning algorithm filters the surrounding noise and excludes background pixels on raw images for MR DWI series. 218 cases, 28 cases, and another set of 28 cases from multiple institutions were respectively used for the algorithm training, validation and testing, with a good representation of the intended use population in terms of gender and age. Furthermore, the test database was constructed with cases coming from different institutions than the training and validation set.

The analysis was performed based on the information available in the DICOM metadata of the cases. DICOM data used were sourced from the following manufacturers: Siemens, General Electric, Philips and Canon.

The reference standard was established by manual segmentation performed by expert clinicians. The final model complies with the acceptance criteria based on the Dice on test dataset for brain tissue class.

C. Substantial Equivalence

The subject device MR DWI/FLAIR Measurement V1.0 is a subset of the predicate device, Olea Sphere V3.0 (Diffusion and Analysis modules). Both MR DWI/FLAIR Measurement V1.0 and Olea Sphere® V3.0 are user-defined software analysis tools used for the analysis of MR DWI and FLAIR studies. Both the MR DWI/FLAIR Measurement V1.0 and the Olea Sphere V3.0 are intended for use in healthcare facilities and by the same users; both subject and predicate devices are intended for use by trained professionals. Patient management decisions should not be based solely on the results of either software. Therefore, the intended use of the software is the same.

The MR DWI/FLAIR Measurement V1.0 and Olea Sphere V3.0 have substantially equivalent features as they both:

- provide processing capabilities for the analysis of MR series;
- are designed to be able to process MR DWI and FLAIR series;
- are able to provide same outputs;
- are able to extract voxel values from relative and normalized FLAIR maps.

The four minor differences between the two devices are:

- In the intended use / indications for use: The MR DWI/FLAIR Measurement V1.0 represents a subset of the Olea Sphere V3.0. Accordingly, the indication for use of the subject MR DWI/FLAIR Measurement V1.0 is considered substantially equivalent to that of the Diffusion and Analysis modules, subset of that of the Olea Sphere V3.0;
- In the technical characteristics, the three differences are:
    - Olea Sphere V3.0 is equipped with a visualization interface whereas MR DWI/FLAIR Measurement V1.0 needs to communicate with the technical platform to visualize the outputs.

- The second difference is related to an algorithm applied before maps computation:

  MR DWI/FLAIR Measurement V1.0 uses a Diffusion Brain Extraction Tool (BET) based on AI algorithms. It must be noted that this algorithm is identical to the recently FDA cleared MR Diffusion Perfusion Mismatch V1.0's one (K223502). This difference does not impact the calculation method of the outputs.

- The third difference is that relative and normalized FLAIR values are automatically calculated into the subject device whereas, in the predicate, voxels values are exported to an Excel file and then relative and normalized FLAIR values are manually calculated.

However, these minor differences do not impact the safety or effectiveness of the subject device. Comparative testing has been performed to demonstrate substantial equivalence in safety and effectiveness between the MR DWI/FLAIR Measurement V1.0 and the relative subset within the Olea Sphere V3.0.

Table 1: Substantial equivalence comparison table

MR DWI/FLAIR Measurement V1.0	**Olea Sphere® V3.0 (K152602)**
ADC map computation	YES
Hypointense area segmentation on ADC map	YES
ADC hypointense area and symmetric contralateral volume segmentations on FLAIR series	YES
Relative and normalized FLAIR maps computation	YES

D. Summary of Performance Testing

MR DWI/FLAIR Measurement V1.0 has been validated to ensure that the system meets all performance specifications necessary to operate according to its intended use and in a manner substantially equivalent to the predicate device.

The following performance evaluations were conducted:

- Product risk assessment;
- Software modules verification tests;
- Software validation test;
- Comparative clinical image study.

Based on the clinical performance as documented in the comparative clinical image study, the MR DWI/FLAIR Measurement V1.0 has a safety and effectiveness profile that is substantially equivalent to the predicate device. Below summarizes the testing results:

Relative FLAIR: As shown in the relative FLAIR Bland-Altman analysis, the average estimated bias (average of differences) was close to zero (0.004). Furthermore, Bland-Altman analysis estimates that 95% of the measurement differences ranged between -0.013 and +0.021 (considered as the maximum of the 95% limits of agreement).

DICE indexes between ADC hypointense area segmentations on FLAIR images generated with both devices were excellent, ranging from 0.816 to 0.976.

Normalized FLAIR: As shown in the normalized FLAIR Bland-Altman analysis, the average estimated bias (average of differences) was close to zero (0.05). Furthermore, Bland-Altman

analysis estimates that 95% of the measurement differences ranged between -0.100 and +0.199 (considered as the maximum of the 95% limits of agreement).

DICE indexes between both devices were excellent and equal to those found in the relative FLAIR analysis, i.e., ranging from 0.816 to 0.976.

E. Conclusions

MR DWI/FLAIR Measurement V1.0 is substantially equivalent to the predicate device, Olea Sphere® V3.0. The MR DWI/FLAIR Measurement V1.0 has the same intended use and similar indications for use, technological characteristics, and principles of operation as its predicate device.

In addition, the minor technological differences between the MR DWI/FLAIR Measurement V1.0 and its predicate devices raise no new questions of safety or effectiveness. Performance data demonstrate that the MR DWI/FLAIR Measurement V1.0 is as safe and effective as the Olea Sphere® V3.0. Thus, the MR DWI/FLAIR Measurement V1.0 is substantially equivalent.